Exhibit F

Court File No. 00-CV-195906CP

ONTARIO

SUPERIOR COURT OF JUSTICE

B E T W E E N:

YVONNE ANDERSEN on her own behalf and as Executrix of the Estate of Erik Andersen, SHARON FROST and HER MAJESTY THE QUEEN IN RIGHT OF THE PROVINCE OF ALBERTA, as represented by the MINISTER OF HEALTH AND WELLNESS

Plaintiffs

- and -

ST. JUDE MEDICAL, INC. and ST. JUDE MEDICAL CANADA, INC.

Defendants

Proceeding under the Class Proceedings Act, 1992.

--- This is Day 10 in the trial proceedings held before the Honourable Madam Justice Joan Lax, at the Superior Court of Justice, 393 University Avenue, Courtroom 807, Toronto, Ontario, on the 3rd day of March, 2010 commencing at 12:00 p.m.

REPORTED BY: Kimberley Neeson

RPR, CRR, CSR, CCP, CBC

A P P E A R A N C E S :

Sandra Barton, Ms.,
Angus T. McKinnon, Esq., for the Plaintiffs.

Gordon McKee, Esq.,
Jill Lawrie, Ms.,
Marcy McKee, Ms.
Karin McCaig, Ms., for the Defendants.

Also present: Brenda Lytwyn (Law Clerk - Blakes)
Gail Oxtoby (Law Clerk - Heenan)

I N D E X

R U L I N G

THE HONOURABLE MADAM JUSTICE JOAN LAX:

This action concerns the alleged negligent conduct of St. Jude Medical Inc. in the pre-market research and development, design and testing, manufacture, distribution and sale of a mechanical heart valve coated with Silzone, and the post-market monitoring, recall and warning to regulators, health care professionals and the public.

The St. Jude Silzone valve was approved for sale in Canada by Health Canada in July 1997 and in the United States by the U.S. Food & Drug Administration in March 1998. The action is brought on behalf of persons resident in Canada, other than British Columbia or Quebec, who had one of the Silzone valves or annuloplasty rings implanted, and on behalf of their family members, prior to the worldwide recall of these devices on January 21, 2000.

The plaintiffs allege, among other things, that St. Jude made representations to regulators regarding the safety and efficacy of the Silzone valve that were false, unsupported or unsupportable, and that it failed to disclose

sufficient information to regulators relating to Silzone's safety and efficacy.

The trial is expected to be lengthy and will involve complex technical and scientific evidence. The parties have completed their opening statements and the plaintiffs have adduced the evidence of the representative plaintiffs. The plaintiffs now propose to call Dr. Suzanne Parisian as their first expert witness, and I have been asked to rule on the admissibility of her evidence.

Dr. Parisian has testified as to her qualifications and has been cross-examined. Her curriculum vitae has been marked as Exhibit 31. I have reviewed her two reports and I have heard comprehensive submissions on the admissibility of her evidence.

To be admissible, expert evidence must meet the following criteria set out by Sopinka, J. in Regina v. Mohan, [1994] 2 S.C.R. 9:

(1) the evidence must be relevant;

(2) the evidence must be necessary to assist the trier of fact;

(3) there must be no exclusionary rule otherwise prohibiting the receipt of the evidence;

and (4) the evidence must be given by a

properly qualified expert.

Our appellate courts have emphasized that the trial court performs an important gatekeeper role and the evidence should be scrutinized at the time it is proffered. An "anything goes" approach to the admissibility of expert evidence is no longer acceptable. The dangers of this approach were well expressed by Justice Moldaver in Johnson v. Milton (Town) (2008), 91 O.R. (3d) 190 (C.A.) at paragraphs 49 and 50 when he said:

> "Apart from trial economy, trial judges who fail to properly perform their gatekeeper function run the risk of having their decision-making function usurped or severely eroded by 'expert generalists' who profess to know something about everything and who are only too willing to provide the court with a ready-made solution for any contentious issue that might exist. The problem with such witnesses is that while they appear knowledgeable and generally come

across well, upon closer scrutiny, their opinions may well turn out to be little more than concoctions consisting of guesswork, speculation, commonplace information and junk science with a hint of valid science thrown in for good measure.

Courts must be vigilant to guard against such impermissible evidence. It is trite law that expert witnesses should not give opinion evidence on matters for which they possess no special skill, knowledge or training, nor on matters that are commonplace, for which no special skill, knowledge or training is required."

The plaintiffs seek to have Dr. Parisian qualified as an expert and give opinion evidence on the practices and procedures employed by the U.S. Food & Drug Administration in approving a medical device, including determining its safety and efficacy, the disclosure required of a manufacturer in seeking approval, the kinds of

investigations to be expected of an applicant, whether St. Jude fulfilled these obligations under U.S. federal law during the pre-approval and post-approval process, and if it did not do this, what actions the FDA could or would have taken.

The defendants raise two broad categories of objections to Dr. Parisian's proposed testimony. First, they submit that Dr. Parisian has not been shown to have acquired special or peculiar knowledge that qualifies her to testify on the standards and practices of the United States Food & Drug Administration relating to the approval of a mechanical heart valve, including the disclosure obligations of a manufacturer, whether these obligations were fulfilled, and if they were not, what action the FDA would or could have taken had there been compliance.

Second, they submit that Dr. Parisian's opinions with respect to St. Jude's post-approval compliance with U.S. regulatory requirements with respect to labelling, marketing and reporting of adverse events are not relevant to the issues in this action and are not necessary to assist the court and constitute inadmissible opinion evidence.

Dr. Parisian is a medical doctor with

specialist qualifications in pathology who received board certification in anatomic and clinical pathology in 1989. Between 1991 and 1995 she was employed with the United States Public Health Service and assigned to the Food & Drug Administration. Between 1991 and 1993 she was a medical officer in the Office of Health Affairs providing primary support to the Office of Compliance and responsible for overseeing the safety of medical devices already approved and marketed in the United States. Between 1993 and 1995 she served as one of two chief medical officers in the FDA's Office of Device Evaluation within the FDA's Centre for Devices and Radiological Health. This centre oversees and evaluates new product marketing applications for medical devices not yet on the United States market.

The Office of Device Evaluation has a number of divisions. Dr. Parisian's assignment was in the Division of Reproductive, Abdominal, Ear, Nose & Throat, and Radiology. Her curriculum vitae contains a long list of devices for which she had clinical responsibilities as a medical officer in the FDA's Office of Device Evaluation, but she

never had clinical responsibilities for mechanical heart valves. That responsibility was in a different division of the Office of Device Evaluation. This was the Division of Cardiovascular, Respiratory and Neurology, whose Chief Medical Officer was Dr. Wolf Sapirstein, a cardiovascular surgeon. This was the division within the Office of Device Evaluation that reviewed St. Jude's pre-market approval application supplement for the St. Jude mechanical heart valve with a sewing cuff coated with Silzone.

Dr. Parisian did not work with any of the reviewers who had responsibility for the approval of mechanical heart valves, including the Silzone valve at issue in these proceedings. Her only experience with mechanical heart valves was during her assignment to the Office of Health Affairs between 1991 and 1993 when a safety issue arose with the Bjork Shiley valve. She testified that she came in at the end of that issue and her role was basically one of communication to physicians regarding safety issues with that valve.

After leaving the FDA, Dr. Parisian founded a company, MD Assist, and her husband, who is also a medical doctor, are its two employees.

MD Assist is a regulatory and medical consulting firm that works with medical device manufacturers, mainly start-ups, to help bring new products to the U.S. market and assists with product and marketing development. Dr. Parisian has never consulted to a manufacturer of a mechanical heart valve.

In 2001 she self-published a book, "FDA, Inside and Out." Her curriculm vitae lists four publications; none are related to cardiovascular issues in general or heart valves in particular. Her last publication was in 1996.

Dr. Parisian maintains her medical licence, but her clinical practice ended in the late 1980s and her last work as a pathologist was in 1995.

In recent years, her work has largely been in what she describes as litigation support, that is, in providing expert opinion evidence in court proceedings in the United States, mainly on behalf of plaintiffs. She has not been qualified as an expert witness on the topic of submissions to the FDA on mechanical heart valves, or as an expert witness in U.S. proceedings on the St. Jude Silzone heart valve.

In her report, Dr. Parisian opines

broadly on FDA practices relating to the approval of mechanical heart valves, although she has never reviewed a heart valve submission. She was not part of the FDA's decision-making process relating to the approval and oversight of St. Jude's Silzone coated mechanical heart valve. She was not one of the authors of the FDA's 1994 Heart Valve Guidance document and did not work with it on a day-to-day basis while at the FDA. This document was developed by the FDA to assist industry and reviewers on applications such as the one at issue in this proceeding. She read this document for the first time in preparing her opinion for this litigation.

Dr. Parisian has general knowledge and experience about the practices and procedures of the FDA for the approval of medical devices, but she has no knowledge or experience relevant to the safety and efficacy of a mechanical heart valve that would inform the practices and procedures of the FDA in approving this kind of device.

In her report, Dr. Parisian opines that St. Jude failed to comply with various pre-market disclosure obligations including with respect to its sheep studies, the leaching of silver from the

Silzone coated sewing cuff, and the extent of medical literature that St. Jude provided to the regulator. She further opines on what the FDA might have done in reviewing and approving St. Jude's application had St. Jude provided FDA with this information.

In cross-examination, Dr. Parisian agreed that she has never designed or analyzed a sheep or prosthetic valve implant study. She has not taught, studied or written on the effects of silver on bacteria in human cells. She has no specialized knowledge in toxicology, biomaterials science, cardiology or microbiology.

The science behind mechanical heart valves, the testing of these valves to determine safety and efficacy and the interpretation of test results are matters that are technical and complex. Other witnesses who do have this knowledge will be testifying in this trial and will be able to provide the court with the evidence it requires to make the necessary factual determinations as to whether or not St. Jude's conduct met or failed to meet the standard of care in seeking U.S. regulatory approval for the Silzone valve.

A properly qualified expert may provide

an opinion as to what material information bears on the safety and efficacy of the Silzone coated heart valve and may assist the court in understanding these matters so that the court can make informed findings as to whether the representations made by St. Jude were false or misleading, and whether the defendants' disclosure was full and truthful.

Dr. Parisian's generalized knowledge acquired during her two years as a medical officer with clinical responsibilities for the approval of other medical devices does not qualify her to offer an opinion about the approval or decision-making process for a different device in a different division of the Office of Device Evaluation.

In summary, on the objection with respect to qualifications, Dr. Parisian is not qualified to testify about the standards and practices of the FDA relating to the pre-market approval process for the St. Jude Silzone heart valve. Dr. Parisian is not a properly qualified expert on this subject and any evidence she can give about FDA practices with respect to the approval of other medical devices will not assist the court in evaluating St. Jude's conduct in the FDA approval process. Her evidence on these issues

is therefore not admissible.

I turn then to the second aspect of Dr. Parisian's proposed evidence relating to post-approval compliance with FDA requirements. The breaches that Dr. Parisian alleges are specific to regulations under the U.S. Federal Food, Drug, and Cosmetic Act ("FDCA") and FDA requirements. These sections of her report focus to a large extent on the marketing restrictions placed on St. Jude by the FDA, the FDA-approved labelling of the Silzone coated valve in the United States, and reporting of adverse events to the FDA.

To a lesser extent, she comments on alleged breaches of various specific FDA regulations such as those that relate to the content of annual reports and PMA supplements.

These opinions can only be relevant if they are relevant to the common issues that are to be resolved in this action. There is no common issue that addresses breaches of U.S. regulatory law with respect to labelling, marketing and reporting. Neither party alleges that there was marketing in the United States in compliance with or in breach of U.S. law. Neither party alleges there was compliance with or breach of marketing

conditions in the U.S. or whether the heart valve was "misbranded" under U.S. law.

While the fact of adverse events and the steps St. Jude took or failed to take to report adverse events is pleaded, neither party pleads breach of or compliance with U.S. law for reporting adverse events, nor does either party plead breach of or compliance with any other U.S. reporting requirements.

The alleged deficiencies of St. Jude described in Dr. Parisian's reports are largely introduced to establish that, in her opinion, there was a breach of the U.S. FDCA regulations and/or the FDA's conditions of approval. She then relies on her conclusion to discuss the regulatory and legal consequences in the U.S. that would flow from any such breach.

Dr. Parisian is not a lawyer and her role at FDA did not entail providing legal opinions, but rather providing her clinical perspective on public safety issues in instances of alleged non-compliance. She is not qualified to provide expert evidence to assist the court with proving the content of U.S. law or opining on the interpretation of these laws so as to conclude that

St. Jude was in violation of the U.S. FDCA regulations and/or FDA's conditions of approval. In any event, the plaintiffs have not pleaded any breach of foreign law in their claim.

Even if Dr. Parisian were qualified to provide an opinion on compliance with U.S. federal law, this evidence is irrelevant. One of the ultimate questions for the court will be whether the defendants met the standard of care in Canada with respect to the sale and marketing of Silzone coated products.

Another of the ultimate questions for the court will be whether, given the information and knowledge of the defendants regarding the clinical experience with the Silzone heart valve, their conduct was reasonable on the standard applicable to class members' claims, all of whom are Canadian.

There is no evidence or suggestion in Dr. Parisian's reports of Canadian adoption of the U.S. FDCA regulations or the FDA conditions of approval which are largely based on these regulations. Dr. Parisian fairly acknowledges she has little, if any, knowledge of Canadian regulatory law that addresses these topics.

Canada has its own regulatory regime set out in the Medical Device Regulation that includes specific requirements for the content of product labels, marketing materials, the timing and content of adverse event reports and the circumstances in which other reports and filings to the regulator are required. To consider U.S. FDCA regulations or conditions of approval in determining the appropriate standard of care for the defendants' conduct in Canada would be to give effect to foreign legal obligations through the vehicle of tort law.

Foreign statutes and regulations, which represent statements by a foreign legislature about appropriate standards in that jurisdiction, cannot speak to what is an appropriate standard or what is reasonable in Canada. It is that standard that must be applied to the claims of class members in this action.

In Johnson & Johnson Inc. (c.o.b. as McNeil Consumer Products Co.) v. Bristol-Myers Squibb Canada Inc., [1995] O.J. No. 2230, (General Division), the differences in values between Canada and the U.S. were discussed in the context of Health Canada and the FDA reaching different

conclusions on the same issues. The court said at paragraph 11:

> "In determining the issues before this court however, it must be borne in mind that Canada is an independent and sovereign nation with its own made-in-Canada administrative tribunals that have the right to make decisions that are right for Canadians, decisions that reflect Canadian values and regulatory expectations. That being the case, the lack of FDA approval of these advertising claims can have no influence on this court's determination of the issues in litigation, and the plaintiffs' reliance on administrative decisions made abroad is misplaced and inappropriate."

The court does not require Dr. Parisian's opinions on U.S. regulatory law to assess the ultimate questions on product labelling, marketing materials and adverse event reporting and tracking to determine whether the defendants

breached the standard of care owed to Canadian class members.

Further, the evidence regarding labelling materials and marketing activities in the U.S. has, in my view, no relevance or purpose other than to allege that the defendants did not comply with their regulatory obligations in the U.S. In this sense it is akin to character evidence which is generally not admissible. Any probative value it may have is far outweighed by its prejudicial effect as there is the potential for a negative inference to be drawn from allegations of breach of foreign regulatory obligations. This is of no assistance in the fact-finding process relevant to the issues in this trial. The proposed evidence does not meet the Mohan criteria of relevance or necessity and should not be admitted.

Finally, the plaintiffs propose that Dr. Parisian be accepted as an expert to provide testimony on the relationship between international regulatory bodies such as the FDA, Health Canada and the Medical Device Agency in regulating medical devices and reporting on adverse events. Dr. Parisian devotes a page and a half of her almost 100-page report to this topic. The effect of this

evidence is to describe the efforts of five countries, including the U.S., Canada, Australia, the European Union and Japan, to harmonize methods for international cooperation for global medical device regulation and safety.

This evidence is in the nature of fact rather than opinion evidence. It is my understanding that Mr. Butchart, a surgeon from Cardiff, Wales and a witness for the plaintiff, was the first to trigger an alert about the Silzone valve to the United Kingdom Medical Device Agency, and that he and others will speak to this issue for the period 1997 to 2000, which is the period relevant to the issues in this action. As Dr. Parisian left the FDA in 1995, I do not consider it necessary to hear Dr. Parisian's evidence on this point.

For these reasons, I conclude that Dr. Parisian is not qualified to give opinion evidence about the FDA approval process for a mechanical heart valve, or to opine on whether St. Jude fulfilled its disclosure obligations. She is not qualified to opine on what the reviewers of the St. Jude PMA supplement would or would not have done if St. Jude failed to comply with these obligations.

She is also not qualified to testify about U.S. regulatory law, but even if she were qualified, her proposed testimony is not relevant to the issues in this action.

Although Dr. Parisian possesses some special knowledge about FDA practices, she possesses no special knowledge about the FDA approval process for mechanical heart valves, and her report and proposed testimony go well beyond her areas of expertise and can be of no assistance to the court in resolving the issues in this action. Her evidence is therefore inadmissible.

* * * *

MR. MCKINNON: Thank you, Your Honour. I think two things that I'd like to raise. One is I think it would be helpful if we had perhaps 10 minutes to discuss amongst counsel where we go from here, and secondly, I don't know whether you propose releasing that ruling as a formal written ruling, and I'm not saying you need to, but if you're not going to, what I'd appreciate is a direction from Your Honour to the court reporter that she provide us with a transcript of the ruling. We are prepared to pay for it page by page, but I think we should have access to it in one form or the other.

THE COURT: Thank you. I do not propose to do further work on my ruling. I have spoken to the reporter and she will prepare a transcript in the form of a ruling, which I would like to review before its release to the parties, and that will be available to you.

MR. MCKINNON: That would be perfect. Could I suggest that we have 10 minutes?

THE COURT: Certainly.

MR. MCKINNON: Because that may dictate whether or not we're coming back this afternoon. So rather than coming back and dealing with it

then, why don't we see if we can deal with it now.

THE COURT: Mr. McKee?

MR. MCKEE: If we could, Your Honour, on a personal matter, could we meet in chambers when the 10 minutes is up rather than in open court for just a moment?

THE COURT: Certainly.

MR. MCKINNON: And I discussed that with Mr. McKee and I'm quite content.

THE COURT: Absolutely.

MR. MCKEE: We'll speak to the bailiff in 10 minutes.

THE COURT: Is it your intention that I should close court now then?

MR. MCKINNON: I think adjourn court for 10 minutes.

THE COURT: For 10 minutes, and then you want to see me in chambers?

MR. MCKINNON: Correct.

THE COURT: Okay.

-- RECESS AT 12:35 --

-- After an in-chambers hearing, court was adjourned at 12:50 p.m.

REPORTER'S CERTIFICATE

I, KIMBERLEY A. NEESON, RPR, CRR, CSR, CCP, CBC, Certified Shorthand Reporter, certify;

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was put under oath by me;

That the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed;

That the foregoing is a true and correct transcript of my shorthand notes so taken.

Dated this 3rd day of March, 2010.

NEESON & ASSOCIATES
COURT REPORTING AND CAPTIONING INC.
PER:KIM NEESON, RPR, CRR, CSR, CCP, CBC
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